## (NG)Diagnostic Kit for Neisseria Gonorrhoeae Antigen

(Immunochromatography)

**Product Name**

(NG) Diagnostic Kit for Neisseria Gonorrhoeae Antigen (Immunochromatography)

**Intended Use**

The reagent is used to detect the neisseria gonorrhoeae antigen in female cervical swab and male urethral swab qualitatively.

Neisseria gonorrhoeae( Ng ) is the pathogen of gonorrhea. The main symptom of gonorrhea is the purulent infection of the urinary tract, such as urethritis, cervicitis and proctitis. The ill population is mainly young adults and middle-aged, and male patients were more common. The incubation period of Ng is 1-10 days, with an average of 3-5 days. In fact, 60% of women and 5%-20% of men among the infected patients show no clinical symptoms, so that it is important to have a laboratory diagnosis. Immunochromatography detection of chlamydia trachomatis is widely used in clinical diagnosis for its simple operation and quickness comparing to culture method and nucleic acid sequence-based amplification.

**Test Principle**

The test utilizes antibodies including a mouse anti-Ng monoclonal antibody 2 and goat anti-mouse IgG antibody on the nitrocellulose membrane with colloidal gold marked mouse anti-Ng monoclonal antibody 1 as an mark tracer. The reagent is used to detect the Ng according to the principle of double antibody sandwich method and gold immunochromatography assay.

The sample mixing up mouse anti-Ng monoclonal antibody 1–marker move along the membrane to the T line, and form the T line with mouse anti-Ng monoclonal antibody 2 when the sample contains Ng, which a positive result. Conversely, it is a negative result.

**Main Components**

The testing kit is in the form of strip and cassette. Basic components: Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board. Colloidal gold marked pad coated with mouse anti-Ng monoclonal antibody, nitrocellulose membrane coated with mouse anti-Ng monoclonal antibody， control line coated with goat anti mouse IgG antibody. The sample dilution A is made of 0.2M Na(OH), sample dilution B is made of 0.2M HCl.

Materials required but not provided: sample tube, swab (depend on customer's requirement)

Description: different components of different batches cannot be used at the same time to avoid erroneous results

**Storage and Expiry**

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

**Sample Requirement**

Quality of sample is crucial. In order to ensure that there is sufficient amount of microorganisms to be tested in the swab, samples must be collected from infected region (2-4cm inside the female cervical canal or male urethral orifice is the columnar epithelium, which is the most vulnerable area of Ng.)

**Female cervical sampling:** Use a cotton swab to clean the excess mucus outside the cervix before sample collection. Put a swab 1-1.5 cm into the cervix, twist the swab several times and stay for 5-10 seconds before removal.

**Male cervical sampling:** Use male urethral swab for collecting sample. Be sure that there is no urination for at least 2 hours before sample collection. Put a swab 2-4 cm into the cervical, twist the swab several times and stay for 5-10 seconds before removal.

Put the swap into the sample tube if the detection can be carry immediately. Samples may be stored at 2-8℃ for 48h, and at -20 ℃ for 3 months. Frozen refrigerated samples should be recovered to room temperature before detection. Repeat freeze and thaw for only 1 time.

**Test Procedure**

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)

Dealing with samples according to the following method:

Drop 11 drops (300 μL) of sample dilution A vertically into the sample tube, put the swap with sample on it into the tube immediately, squeeze the tube and twist the swab for 15 times, keep the swap stay inside for 2 minutes before removal.

Drop 6 drops (300 μL) of sample dilution B vertically into the sample tube, squeeze the tube and twist the swab for 15 times, keep the swap stay inside for 1 minute before removal. Discard the swab and cover the lid of the tube.

**Operation steps**

**Strip:** 1. Remove the test device from the sealed pouch.

2. Put the end of the test strip print with arrow into the sample, the interface of liquid should not exceed the max line, take it out and place the test device on a clean and level surface after 15 seconds.

3. Observe the test results immediately within 15-20 minutes, the result is invalid over 25 minutes.

**Cassette：** 1. Take off the outer packing, put the cassette onto the desk with the sample window up.

2. Drop 3 drops of diluted sample vertically into the sample hole of cassette.

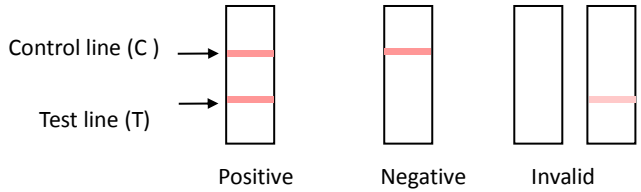
3. Observe the test results immediately within 15-20 minutes, the result is invalid over 25 minutes.

**Result Judgment**

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One red line appears in the control region(C). No apparent red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.




**Limitation**

1. The results of the reagent only demonstrated the presence of neisseria gonorrhoeae antigen in the sample, which is not the only basis for clinical diagnosis and treatment. Neisseria gonorrhoeae antigen may still be retained a short term after the treatment.

2. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.

3. Limited by the detection method, the sensitivity was generally lower than that of the nucleic acid reagent. The experimental personnel should pay more attention to the negative results. If infection is still suspected, the sample should be collected later and carry the detection with nucleic acid detection or isolation and culture identification method.

4. False negative results may occur according to unreasonable sample collection, transportation and sample preparation.

**Performance Characteristics**

1. Using internal quality control samples:

Negative specificity: The results should all be negative when detecting 10 kits of Ng negative quality control samples.

Positive specificity: The results should all be positive when detecting 10 kits of Ng positive quality control samples.( Including strong, medium and weak positive samples)

Limit of detection: Not less than $1\times10^5$ CFU/mL

Precision: The results should be consistent and the coloration degree should be consistent when detecting the precision control samples by 10 kits of the same batch.

2. A clinical evaluation was conducted on 1400 samples comparing the results obtained using the Diagnostic Kit for Neisseria Gonorrhoeae Antigen and other commercially available Ng tests. The results demonstrated a 100% positive agreement.

3. Analytical sensitivity:

Jieeryin ≤20μL/mL, fuyinjie ≤20μL/mL, miconazole ≤5mg/mL, metronidazole ≤5mg /mL, tinidazole ≤5mg /mL, mucoitin ≤10mg /mL, hemoglobin ≤10g/L has no effect on the detection result.

Staphylococcus aureus, candida albicans, escherichia coli, trichomonas vaginalis, S.faecium, S.faecalis, acinetobacter, alpha streptococcus, beta streptococcus, gamma streptococcus, human mycoplasma, bacillus proteus ($10^7$ CFU/mL) and chlamydozoa trachomatis ($10^7$ IFU/mL） showed no cross reactivity.

4. Hook effect: the hook effect will not occur even the Ng concentration is as high as $9.76\times10^6$ copy/mL

**Precaution**

1. For IN VITRO diagnose only.

2. Do not use after the expiration date.

3. The test result is invalid over 25 minutes.

4. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.

5. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.

6. There is no biological safety problem with the product itself, but the testing reagent and the sample still should be treated as an infectious material after use.

7. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.